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U. S. Army Center For Health Promotion and Preventive Medicine (USACHPPM)
Strategic Initiatives Office (SIO), Quality Assurance Team (QAT)

STANDING OPERATING PROCEDURE (SOP)
For
REPORTING TO MANAGEMENT

Preparer — Date: 03 JAN 2001

Supervisor Approval — Date: 1/4/2001

Annual Review

	Date Due	Date Comp.
Preparer	03JAN03	
Supervisor	03JAN03	

	Date Due	Date Comp.
Preparer		
Supervisor		

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applicable to the activities of other organizations.

CONTENTS

I. PURPOSE: The purpose of this Standing Operating Procedure (SOP) is to establish procedures for reporting QAT inspection findings as well as QAT monthly operations and concerns. QAT inspection reports include GLP Critical Phase Audit Reports, Assessors Deficiency Reports, Quarterly Management Reports, and Special Reports.

II. APPLICABILITY: This SOP applies to all USACHPPM QAT personnel.

III. DEFINITIONS:

A. QAT GLP Critical Phase Audit Report (CPAR) – Reports generated by the QAT inspector indicating all discrepancies and/or observations identified during a GLP Critical Phase Audit (CPA).

B. QAT Assessors Deficiency Report (ADR) – Reports generated by the QAT inspector indicating all discrepancies and/or observations identified during a DLS A2LA audit, ISO/IEC Guide 25 method audit or ISO 9000 inspection. This report may also include recommendations for corrective actions, if applicable.

C. QAT Quarterly Management Report (QMR) – A quarterly report generated by the QAT that summarizes all deficiencies, observations, and recommendations identified in the ADRs.

D. Special Report – A report for various types of inspections of contract laboratories or other organization external to USACHPPM.

IV. PROCEDURES:

A. QAT GLP CPAR.

1. GLP CPAs are conducted according to QAT SOP 6.X.
2. GLP CPARs are prepared in memorandum form and forwarded through the Chief, Quality Systems Office, the Director, Toxicology and addressed to the appropriate DTOX Program Manager. A copy is furnished to the Study Director, Institutional Animal Care and Use Committee Chairman (IACUC), and the DTOX GLP Coordinator.
3. The checklist used to perform the inspection is signed by the inspector and the Study Director and/or Principal Investigator. A copy of the checklist is attached to the CPAR.
4. GLP Critical Phase Audit Reports shall include but not be limited to;
    a. Identification of protocol number, study director, test substance, critical phase audited, the date audited and a corrective action suspense date.
    b. A QAT report number generated by assigning a number that corresponds to the actual audit date. For example, if two audits were conducted on 1 Jan 95 their respective numbers would be 950101-1 and 950101-2.
    c. A list of the audit findings, recommendations to address the findings and any management action required to ensure audit findings are addressed. The audit findings shall be referenced to the GLP regulation paragraph, protocol section, SOP section, or other process/procedure that is non-compliant. All QAT GLP CPARs remain as Aopen issues≅ until written corrective action has been received by the QAT. The date the corrective action is received by the QAT is the Adate closed≅.
    d. The original QAT GLP CPAR memorandum is returned to the QAT with the corrective actions, if applicable. The original memorandum must include initials of the appropriate management, indicating acknowledgement of findings. The QAT inspector will file the original memorandum in accordance with QAT SOP 9.X.
    e. An example GLP CPAR is provided in Appendix A.

B. QAT ADR.

1. A QAT ADR will contain at a minimum:
    a. The inspection date, location of audit, and identification of the auditor(s),
    b. A list of the regulations, standards, or other documents used to conduct the audit,

c. A list of the non-conformities noted during the audit or a statement indicating that no deficiencies were found,

d. The audit non-conformities shall be referenced to the A2LA/ISO Guide 25 paragraph, ISO9001 requirement, SOP section, or other process/procedure that is non-compliant,

e. The QAT audit report number, assigned consecutively and consisting of the date (yymmdd) followed by the consecutive inspection number (for example the first inspection conducted on January 2nd 1992 would be designated ADR # 920102-01),

f. Signature block of the auditor(s),

g. An example of a ADR is provided in Appendix B.

2. The audit report shall identify positive findings a s well as non-conformities,

C. **QAT QMR.**

1. Quarterly Management Reports are prepared in memorandum form and forwarded through the Chief, QAT for the following distribution;

   a. Commanding General.

   b. Deputy For technical Services.

   c. Director, Laboratory Sciences.

   d. Director, Toxicology.

2. The remaining directorates will receive distribution only when the QMR contains information pertaining to their operations.

3. The QMR will contain at a minimum the following:

   a. Current issues and/or any concerns affecting quality that may require management attention. They shall be identified in accordance with various regulations and standards to include GLP, ISO9000, ISO/IEC Guide 25, A2LA, COLA, etc.,

   b. A table of all GLP CPARs summarizing findings. The table shall contain the GLP CPAR number, protocol number, point of contact, test substance, date of audit, summarized audit findings, QAT recommendations, management action required and the date closed. GLP CPARs are dropped from the table when they become Aclosed≅ and after the next QAT QMR,

   c. A table summarizing DLS Customer Comment /Complaint issues,

   d. A table summarizing A2LA and/or ISO 25 Audit findings,

   e. And, any major accomplishments with respect to quality.

4. The QAT QMR will be distributed on or before the tenth working day of each quarter.

D. Special Reports. Special Reports shall be customized to address specific standards and/or regulations used to conduct the audit. Special Reports shall contain at a minimum the following information:

1. The inspection date, location of audit, and identification of the auditor(s),
2. A list of the regulations, standards, or other documents used to conduct the audit,
3. A list of the non-conformities noted during the audit or a statement indicating that no deficiencies were found,
4. The audit non-conformities shall be referenced to the A2LA/ISO Guide 25 paragraph, ISO9001 requirement, SOP section, or other process/procedure that is non-compliant,
5. The QAT audit report number, assigned consecutively and consisting of the date (yymmdd) followed by the consecutive inspection number (for example the first inspection conducted on January 2nd 1992 would be designated ADR # 920102-01),
6. The audit report shall identify positive findings as well as non-conformities,
7. Signature block of the auditor(s),
8. An example of a Special Report is provided in Appendix D.

V. SAFETY CONSIDERATIONS: Safety was considered, but there are no requirements at this time.

VI. REFERENCES:

A. Goldman, Dexter S. Good Laboratory Practices, Course Manual. East Brunswick, New Jersey: The Center for Professional Advancement, Mar 1992.

B. Victoria Group, Ltd., The. Internal Auditor Training Program. England: CEEM, 1992.

C. DataChem Laboratories. Quality Assurance and Environmental/Occupational Health Monitoring. Salt Lake City, Utah: Dept. of Family and Preventive Medicine, 1991.